

- IFU 1644 \$
PATENT
ATTORNEY DOCKET: 59046.000033

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application Number : 09/171,909 Confirmation No.: 8638
Applicant : Jayanta ROY-CHOWDHURY
Filed : May 9, 2001
Title : NOVEL PROCESSES IMPLEMENTING SELECTIVE IMMUNE DOWN
REGULATION (SIDR)
TC/Art Unit : 1644
Examiner: : Ronald B. Schwadron

Docket No. : 59046.000033
Customer No. : 21967

MAIL STOP AMENDMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, and in compliance with the duty of disclosure set forth in 37 C.F.R. § 1.56, Applicants submit attached Form PTO-SB/08A (modified) for consideration and request the references cited therein be made of record by the U.S. Patent and Trademark Office (the "USPTO") in the above-captioned application.

In accordance with 37 C.F.R. § 1.98(a)(2)(ii), copies of cited U.S. patents and/or U.S. patent application publications are not being provided.

Applicants point out the following six (6) applications that are co-pending with the instant Application at the USPTO and listed in the attached Form PTO/SB/08A:

US 2003-0170258 A1, published 09-11-2003 (Roy-Chowdhury, et al.);
US 2004-0022768 A1, published 02-05-2004 (Roy-Chowdhury, et al.);
US 2004-0023909 A1, published 02-05-2004 (Roy-Chowdhury, et al.);
Co-pending U.S. Appl. No. 09/356,294, filed July 16, 1999 (Roy-
Chowdhury, et al.) (unpublished);
Co-pending U.S. Appl. No. 09/447,704 filed May 9, 2001 (Roy-
Chowdhury, et al.) (unpublished); and
Co-pending U.S. Appl. No. 11/378,158, filed March 16, 2006
(unpublished).

04/26/2006 JADD01 00000001 09171909

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Applicants respectfully point out that the submission of the listed references in this Information Disclosure Statement is not an admission that they are prior art or that they are material to patentability of any claims of the application. Also, the submission of this Information Disclosure Statement is not an indication that a search has been made by Applicants.

For the convenience of the Examiner in considering the cited references, a copy of each of the cited references is enclosed with this communication. In considering the cited references, it may be noted by the Examiner that certain of the references may contain markings, underlinings, and/or other notations. These markings, underlinings, and/or other notations are not to be construed as drawing the Examiner's attention either to selected parts or away from other parts of the cited references. Any such markings were either present on the copies of the cited references obtained by the associated individuals, or were made thereon during the study of the references by the associated individuals.

Consideration of the foregoing plus the prompt return of a copy of the enclosed Form SB/08A with the Examiner's initials in the left column in accordance with MPEP § 609 are respectfully requested.

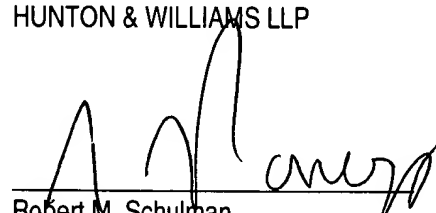
This Information Disclosure Statement is being submitted after the mailing of a non-final Office Action, but is believed to be prior to a final Office Action or a Notice of Allowance. Pursuant to 37 C.F.R. § 1.97(c)(2), a check in the amount of \$180.00 as set forth in § 1.17(p) is enclosed. In the event any variance exists between the amount enclosed and the Patent Office charges, please charge or credit any difference to the undersigned's Deposit Account No. 50-0206.

Respectfully submitted,

HUNTON & WILLIAMS LLP

Dated: April 25, 2006

By:


Robert M. Schulman
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**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

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Application Number	09/171,909
Filing Date	May 9, 2001
First Named Inventor	Roy-Chowdhury
Art Unit	1644
Examiner Name	Ronald B. Schwadron
Attorney Docket Number	59046.000033

Sheet 1 of 7

U.S. PATENT DOCUMENTS

*Examiner Initials	Cite No.	DOCUMENT NUMBER Number - Kind Code (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	1.	US- 5,788,968	08-04-1998	Weiner	
	2.	US- 2003-0170258 A1	09-11-2003	Roy-Chowdhury, et al.	
	3.	US- 2004-0022768 A1	02-05-2004	Roy-Chowdhury, et al.	
	4.	US- 2004-0023909 A1	02-05-2004	Roy-Chowdhury, et al.	
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		US-			

FOREIGN PATENT DOCUMENTS

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		Country Code Number-Kind Code (if known)					YES	NO
	5.	WO	94/27622	12-08-1994	Beschorner		<input type="checkbox"/>	<input type="checkbox"/>
	6.	WO	98/37917	09-03-1998	Roy-Chowdhury, et al.		<input type="checkbox"/>	<input type="checkbox"/>
	7.	EP	0 914 163	05-12-1999	Roy-Chowdhury, et al.		<input type="checkbox"/>	<input type="checkbox"/>
							<input type="checkbox"/>	<input type="checkbox"/>
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							<input type="checkbox"/>	<input type="checkbox"/>

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*Examiner Initials	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	TRANSLATION	
			YES	NO
	8.	Abandoned U.S. Appl. No. 08/808,629 filed February 28, 1997 (Roy-Chowdhury, et al.) (unpublished).	<input type="checkbox"/>	<input type="checkbox"/>
	9.	Co-pending U.S. Appl. No. 09/447,704 filed November 23, 1999 (Roy-Chowdhury, et al.) (unpublished).	<input type="checkbox"/>	<input type="checkbox"/>
	10.	Co-pending U.S. Appl. No. 09/356,294, filed July 16, 1999 (Roy-Chowdhury, et al.) (unpublished).	<input type="checkbox"/>	<input type="checkbox"/>
	11.	Co-pending U.S. Appl. No. 11/378,158, filed March 16, 2006 (unpublished).	<input type="checkbox"/>	<input type="checkbox"/>
	12.	European Search Report dated June 29, 2001 for European Application No. EP 98912887.1, filed February 26, 1998.	<input type="checkbox"/>	<input type="checkbox"/>
	13.	European Search Report dated August 22, 2001 for European Application No. EP 00115423.6, filed February 26, 1998.	<input type="checkbox"/>	<input type="checkbox"/>
	14.	February 8, 2005 Translation of Substantive Examination Report (redacted) citing two (2) references for Israeli Patent Appl. No. 126,714.	<input type="checkbox"/>	<input type="checkbox"/>
	15.	International Search Report dated June 23, 1998 for International Application No. PCT/US98/03606, filed Feb. 26, 1998.	<input type="checkbox"/>	<input type="checkbox"/>
	16.	International Search Report dated September 15, 2004 for International Application No. PCT/US03/33178, filed October 17, 2003.	<input type="checkbox"/>	<input type="checkbox"/>
	17.	Ali et al., "The use of DNA viruses as vectors for gene therapy," <u>Gene Therapy</u> , 1:367-384 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	18.	Baggi, et al., "Oral Administration of an Immunodominant T-cell Epitope Downregulates Th1/Th2 Cytokines and Prevents Experimental Myasthenia Gravis", The Journal of Clinical Investigation, Vol. 104, No. 9, pg. 1287-1295, November 1999.	<input type="checkbox"/>	<input type="checkbox"/>

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			YES	NO
	19.	Benjamini, E. and Leskowitz, S. (Eds.), "Transplantation Immunology," Immunology: A Short Course, Ch.19, 347-367 (Wiley-Liss, Inc. 2nd ed. 1991).	<input type="checkbox"/>	<input type="checkbox"/>
	20.	Cantor, H.M. and Dumont, A.E., "Hepatic Suppression of Sensitization to Antigen Absorbed into the Portal System," <u>Nature</u> , 215:744-745 (1967)	<input type="checkbox"/>	<input type="checkbox"/>
	21.	Clare-Salzler et al., "Prevention of Diabetes in Nonobese Diabetic Mice by Dendritic Cell Transfer," <u>J. Clin. Invest.</u> , 90:741-748 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	22.	Dai et al., "Cellular and humoral immune responses to adenoviral vectors containing factor IX gene: Tolerization of factor IX and vector antigens allows for long-term expression," <u>Proc. Natl. Acad. Sci. USA</u> , 92:1401-1405 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	23.	Engelhardt et al., "Ablation of <i>E2A</i> in recombinant adenoviruses improves transgene persistence and decreases inflammatory response in mouse liver," <u>Proc. Natl. Acad. Sci. USA</u> , 91:6196-6200 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	24.	Eron et al., "Randomised trial of MNrgp120 HIV-1 vaccine in symptomless HIV-1 infection," <u>The Lancet</u> , 348:1547-1551 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	25.	Fang et al., "Gene Therapy for Hemophilia B: Host Immunosuppression Prolongs the Therapeutic Effect of Adenovirus-Mediated Factor IX Expression," <u>Human Gene Therapy</u> , 6:1039-1044 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	26.	Fauci, A., "Host factors and the pathogenesis of HIV-induced disease," <u>Nature</u> , 384:529-534 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	27.	Fukushima et al., "Effects of Cyclosporin A on the Induction of Oral Tolerance," <u>Oral Tolerance: Mechanisms and Applications: Annals of the New York Academy of Sciences</u> , 778:376-378 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	28.	Graham et al., <u>Methods in Molecular Biology</u> , 109-128 (The Human Press 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	29.	Guidotti et al., "High-Level Hepatitis B Virus Replication in Transgenic Mice," <u>J. Vir.</u> , 69(10):6158-6169 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	30.	Guzzetta et al., "Induction of Kidney Transplantation Tolerance Across Major Histocompatibility Complex Barriers by Bone Marrow Transplantation in Miniature Swine," <u>Transplantation</u> 51(4):862-866 (1991).	<input type="checkbox"/>	<input type="checkbox"/>

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			YES	NO
	31.	Hancock et al., "Short Communication: Suppression of Insulinitis in Non-Obese Diabetic (NOD) Mice by Oral Insulin Administration Is Associated with Selective Expression of Interleukin-4 and -10, Transforming Growth Factor-beta, and Prostaglandin-E," Am. J. Path., 147(5):1193-1199 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	32.	Hirahara et al., "CD4+ T Cells Anergized by High Dose Feeding Establish Oral Tolerance to Antibody Responses when Transferred in SCID and Nude Mice," J. Immunol., 154:6238-6245 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	33.	Horwitz et al., "Synthesis and Assembly of Adenovirus 2: I. Polypeptide Synthesis, Assembly of Capsomeres, and Morphogenesis of the Virion," Virology, 39:682-694 (1969)	<input type="checkbox"/>	<input type="checkbox"/>
	34.	Horwitz, M.S., "Adenoviridae and Their Replication," Virology, Ch. 60, 1679-1721 (Raven Press 2nd ed. 1990)	<input type="checkbox"/>	<input type="checkbox"/>
	35.	Ilan et al., "Adoptive Transfer of Tolerance from Rats Centrally Tolerized to Adenoviral Antigens Allows Long-Term Adenovirus-Mediated Gene Therapy in Gunn Rats," Hepatology: AASLD Abstracts, 202A, 304 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	36.	Ilan et al., "Induction of Central Tolerance by Intrathymic Inoculation of Adenoviral Antigens into the Host Thymus Permits Long-term Gene Therapy in Gunn Rats," J. Clin. Invest., 98(11):2640-2647 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	37.	Ilan et al., "Transient Short Term FK-506 Treatment Permits Long Term Gene Expression Using Recombinant Adenoviruses Vectors," J. Hepatol.: Postgraduate Course and Abstracts of the 31st Annual Meeting of the European Association for the Study of the Liver, 23:73, WP3/019 (Supp. 1 1996)	<input type="checkbox"/>	<input type="checkbox"/>
	38.	Jaffe et al., "Adenovirus-mediated in vivo gene transfer and expression in normal rat liver," Nature Genetics, 1:372-378 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	39.	Kerr et al., "Apoptosis: A Basic Biological Phenomenon with Wide-Ranging Implications in Tissue Kinetics," Br. J. Cancer, 26:239-257 (1972)	<input type="checkbox"/>	<input type="checkbox"/>
	40.	Kuby, J., "Cancer and the Immune System," Immunology, 573-596 (W.H. Freeman and Company 3rd ed. 1997)		
	41.	Lederer, J. A. and A. K. Abbas, "Cytokines in Specific Immune Responses," Samter's Immunologic Diseases, Vol. I, Ch. 10, 129-141 (Little, Brown and Company 5th ed. 1995)		

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			YES	NO
	42.	Maeda et al., "Conjugates of Anticancer Agents and Polymers: Advantages of Macromolecular Therapeutics in Vivo," <u>Bioconj. Chem.</u> , 3(5):351-362 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	43.	Madsen et al., "Immunological Unresponsiveness Induced by Recipient Cells Transfected with Donor MHC genes," <u>Nature</u> , 332:161-164 (1988)	<input type="checkbox"/>	<input type="checkbox"/>
	44.	Maizel et al., "The Polypeptides of Adenovirus: II. Soluble Proteins, Cores, Top Components and the Structure of the Virion," <u>Virology</u> , 36:126-136 (1968)	<input type="checkbox"/>	<input type="checkbox"/>
	45.	Moller et al., "Cellular Mechanisms Underlying Differential Rejection of Sequential Heart and Lung Allografts in Rats," <u>Transplantation</u> , 55(3):650-655 (1993)	<input type="checkbox"/>	<input type="checkbox"/>
	46.	Müller et al., "Relationship of antibodies against CD4 ⁺ T cells in HIV-infected patients to markers of activation and progression: autoantibodies are closely associated with CD4 cell depletion," <u>Immunology</u> , 79:248-254 (1993)	<input type="checkbox"/>	<input type="checkbox"/>
	47.	Ninomiya, et al., "Intranasal Administration of a Synthetic Peptide Vaccine Encapsulated in Liposome together with an Anti-CD40 Antibody induces Protective Immunity against Influenza A Virus in Mice", <u>Vaccine</u> , Vol. 20, pg. 3123-3129, 2002.	<input type="checkbox"/>	<input type="checkbox"/>
	48.	Pearson et al., "Induction of Transplantation Tolerance in Adults Using Donor Antigen and Anti-CD4 Monoclonal Antibody," <u>Transplantation</u> , 54(3):475-483 (1992)	<input type="checkbox"/>	<input type="checkbox"/>
	49.	Peters et al., "Characterization and Tissue Specificity of a Monoclonal Antibody Against Human Uridine 5'-Diphosphate-Glucuronosyltransferase," <u>Gastroenterology</u> , 93:162-169 (1987)	<input type="checkbox"/>	<input type="checkbox"/>
	50.	Prevec et al., "Use of Human Adenovirus-based Vectors for Antigen Expression in Animals," <u>J. Gen. Virol.</u> , 70:429-434 (1989)		
	51.	Rosengard et al., "Induction of Specific Tolerance to Class I-Disparate Renal Allografts in Miniature Swine with Cyclosporine," <u>Transplantation</u> , 54(3):490-497 (1992)		
	52.	Roy-Chowdhury et al., "Bilirubin Mono- and Diglucuronide Formation by Human Liver <i>In Vitro</i> : Assay by High-Pressure Liquid Chromatography," <u>Hepatology</u> , 1(6):622-627 (1981)		
	53.	Sachs et al., "Control of Programmed Cell Death in Normal and Leukemic Cells: New Implications for Therapy," <u>Blood</u> , 82(1):15-21 (1993)		

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			YES	NO
	54.	Seglen, P. O., "Preparation of Isolated Rat Liver Cells," <u>Methods in Cell Biology</u> , Vol. 13, Ch. 4, 30-83 (1976)	<input type="checkbox"/>	<input type="checkbox"/>
	55.	Sharabi et al., "Specific Tolerance Induction Across a Xenogeneic Barrier: Production of Mixed Rat/Mouse Lymphohematopoietic Chimeras Using a Nonlethal Preparative Regimen," <u>The Journal of Experimental Medicine</u> , 172:195-202 (1990)	<input type="checkbox"/>	<input type="checkbox"/>
	56.	Smith et al., "New Approaches to Transplantation Tolerance," <u>Transplantation Proceedings</u> , 23(4):2157-2161 (1991)	<input type="checkbox"/>	<input type="checkbox"/>
	57.	Sykes et al., "Bone Marrow Transplantation as a Means of Inducing Tolerance," <u>Seminars in Immunology</u> , 2:401-417 (1990)	<input type="checkbox"/>	<input type="checkbox"/>
	58.	Takahashi et al., "Acute hepatitis in rats expressing human hepatitis B virus transgenes," <u>Proc. Nat. Acad. Sci. USA</u> , 92:1470-1474 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	59.	Takahashi et al., "Long Term Correction of Bilirubin-UDP-glucuronosyltransferase Deficiency in Gunn Rats by Administration of a Recombinant Adenovirus during the Neonatal Period," <u>J. Biol. Chem.</u> , 271(43):26536-26542 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	60.	Thomas et al., "Beneficial Effect of Cyclosporine in Posttransplantation Induction of Unresponsiveness of Renal Allografts in Rhesus Monkeys," <u>Transplantation Proceedings</u> , XX(1):134-136 (Suppl. 1 1988)	<input type="checkbox"/>	<input type="checkbox"/>
	61.	Thompson, C.B., "Apoptosis in the Pathogenesis and Treatment of Disease," <u>Science</u> , 267:1456-1462 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	62.	Towbin et al., "Electrophoretic transfer of proteins from polyacrylamide gels to nitrocellulose sheets: Procedure and some applications," <u>Proc. Natl. Acad. Sci. USA</u> , 76(9):4350-4354 (1979)	<input type="checkbox"/>	<input type="checkbox"/>
	63.	Trotman et al., "Azodipyrrroles of Unconjugated and Conjugated Bilirubin Using Diazotized Ethyl Anthranilate in Dimethyl Sulfoxide," <u>Analytical Biochemistry</u> , 121:175-180 (1982)	<input type="checkbox"/>	<input type="checkbox"/>
	64.	Vandenbark et al., "Definition of Encephalitogenic and Immunodominant Epitopes of Guinea Pig Myelin Basic Protein (Gp-BP) in Lewis Rats Tolerized Neonatally with Gp-BP or Gp-BP Peptides," <u>J. Immunol.</u> , 153:852-861 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	65.	van der Lubben, Inez M. et al., "Chitosan and its Derivatives in Mucosal Drug and Vaccine Delivery", <u>European Journal of Pharmaceutical Sciences</u> , Vol. 14, pg. 201-207, 2001.	<input type="checkbox"/>	<input type="checkbox"/>

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			YES	NO
	66.	Walter et al., "Successful expression of human factor IX following repeat administration of an adenoviral vector in mice," Proc. Natl. Acad. Sci. USA, 93:3056-3061 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	67.	Weiner, H.L. and Mayer, L.F. (Eds.), "Oral Tolerance: Mechanisms and Applications," Annals of the New York Academy of Sciences, Vol. 778 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	68.	Weiner, H.L., "Commentary: Oral tolerance," Proc. Natl. Acad. Sci. USA, 91:10762-10765 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	69.	Winkelstein, A., "Immunosuppressive Therapy," Basic and Clinical Immunology, Ch. 61, 766-779 (Appleton & Lange 7th ed. 1991)	<input type="checkbox"/>	<input type="checkbox"/>
	70.	Wyllie et al., "Cell Death: The Significance of Apoptosis," International Review of Cytology, 68:251-306 (1980)	<input type="checkbox"/>	<input type="checkbox"/>
	71.	Yang et al., "Inactivation of E2a in recombinant adenoviruses improves the prospect for gene therapy in cystic fibrosis," <u>Nature Genetics</u> , 7:362-369 (1994)	<input type="checkbox"/>	<input type="checkbox"/>
	72.	Yang et al., "Cellular and Humoral Immune Responses to Viral Antigens Create Barriers to Lung-Directed Gene Therapy with Recombinant Adenoviruses," <u>J. Virol.</u> , 69(4):2004-2015 (1995)	<input type="checkbox"/>	<input type="checkbox"/>
	73.	Zarling et al., "HIV-infected humans, but not chimpanzees, have circulating cytotoxic T lymphocytes that lyse uninfected CD4 ⁺ Cells," <u>J. Immunol.</u> , 144(8):2992-2998 (1990)	<input type="checkbox"/>	<input type="checkbox"/>
	74.	Zhao et al., "Skin graft tolerance across a discordant xenogeneic barrier," <u>Nature Med.</u> , 2(11):1211-1216 (1996)	<input type="checkbox"/>	<input type="checkbox"/>
	75.	Ziegler, J.L. and Stites, D.P., "Hypothesis: AIDS Is an Autoimmune Disease Directed at the Immune System and Triggered by a Lymphotropic Retrovirus," <u>Clin. Immunol. Immunopathol.</u> , 41:305-313 (1986)	<input type="checkbox"/>	<input type="checkbox"/>

EXAMINER SIGNATURE**DATE CONSIDERED**

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.